UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA	§	
	§	
v.	§	**Criminal No. 4:23-cr-195-2**
	§	
VITAMIN SHACK AND SHAKES, LLC, d/b/a THE SHACK,	§	**INFORMATION**
	§	
Defendant.	§	**[Ct. 1: 21 U.S.C. § 331(k) and 333(a)(1) – Causing a Drug to be Misbranded After Shipment into Interstate Commerce]**

CRIMINAL INFORMATION

THE UNITED STATES ATTORNEY CHARGES:

At all times material to this Information:

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

1. The United States Food and Drug Administration ("FDA") is the agency of the United States responsible for, among other things, enforcing the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* FDA's primary purpose in enforcing the FDCA was to protect the health and safety of consumers in the United States. FDA's responsibilities included regulating the manufacturing, labeling, and distribution of food and drugs shipped or received in interstate commerce. The requirements of the FDCA, in part, are meant to ensure that food and drugs are safe for their intended uses and bear labeling that contains accurate and adequate information.

2. The FDCA defined a "drug" in relevant part, as (1) any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal; (2) any article (other than food) intended to affect the structure or any function of the body; or (3) any

article used as a component of either. 21 U.S.C. § 321(g).

3. Whether an article was a drug was determined by its intended use, which was defined at the time of the offense as "the objective intent of persons legally responsible for the labeling of drugs." The intent was determined by "such person's expressions or may be shown by the circumstances surrounding the distribution of the article." Such intent could be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. 21 C.F.R. § 201.128.

4. The FDCA prohibited the following acts and the causing thereof:

a. The doing of any act with respect to a food or drug, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being adulterated or misbranded, 21 U.S.C. § 331(k).

SARMs

5. Selective Androgen Receptor Modulators ("SARMs") are a class of compounds that had similar properties to anabolic steroids, but were not classified as anabolic steroids under the Controlled Substances Act. The FDA has received adverse events associated with SARMs such as life-threatening conditions, including liver toxicity, heart attack and stroke.

6. SARMs are substances that do not meet the definition of a dietary ingredient under 21 U.S.C. § 321(ff). Products containing the non-dietary ingredients SARMs that are intended to be used for weight loss or to increase muscle mass (structure function claims) are considered to be drugs under the FDCA.

7. Cardarine (GW-501516), Ligandrol (LGD-4033), Ostarine (MK-2866), and Testolone (RAD-140), among others, were SARMs manufactured by PERSON1 in Indictment 4:23-cr-195.

DEFENDANTS' PRODUCTS

8. Ostarine (MK-2866) was a product manufactured by PERSON1 under the label name Jintro Pharmaceuticals, a product line owned, marketed, and sold by **VITAMIN SHACK AND SHAKES ("THE SHACK")**.

THE DEFENDANTS, RELATED INDIVIDUALS, AND ENTITIES

9. **THE SHACK** is a Limited Liability Company and a supplement retail location that is located within the McAllen Division of the Southern District of Texas and elsewhere.

10. PERSON1, by and through one of his companies, created private label products, including, but not limited to Jintro Pharmaceuticals, a product line owned, marketed, and sold by **THE SHACK**.

COUNT 1
CAUSING A DRUG TO BE MISBRANDED AFTER SHIPMENT IN INTERSTATE COMMERCE
(21 U.S.C. §§ 331(k) and 333(a)(1)

11. Paragraphs 1 through 10 are incorporated herein by reference.

12. On or about the dates set forth below, in the Southern District of Texas and elsewhere, Defendant

VITAMIN SHACK AND SHAKES, d/b/a THE SHACK

with Co-Conspirators, known and unknown, did, while the drug was held for sale and after its component had been shipped in interstate commerce, cause the product's labeling to be false and misleading in any particular, in that the labeling falsely stated it was a "research product" when in fact it was intended to be used to increase muscle mass, which act resulted in the drug being misbranded within the meaning of Title 21, United States Code, Section 352(a).

Count	Approximate Date	SPP Product Name	Active Ingredient on Label	Other Labeling
1	May 18, 2020	JINTRO PHARMACEUTICALS MK-2866 Ostarine MK-2866	Ostarine MK-2866	"Research Product"

In violation of 21 U.S.C. §§ 331(k) and 333(a)(1).

NOTICE OF FORFEITURE
28 U.S.C. § 2461(c)

13. Upon conviction of the offenses set forth in Count 1 of this Information, the Defendant, **VITAMIN SHACK AND SHAKES, d/b/a THE SHACK**, shall forfeit to the United States, $175,000 in monetary assets.

14. Pursuant to 21 U.S.C. §334 and 28 U.S.C. §2461(c), the Defendant shall forfeit any quantities of drugs which were misbranded when received in interstate commerce, or while in interstate commerce, or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which were introduced into interstate commerce, in violation of 21 U.S.C. §331. However, pursuant to 21 U.S.C. §853(p), the United States seeks monetary forfeiture equal to $175,000, because such misbranded drugs have been transferred, or sold to, third parties.

ALAMDAR HAMDANI
UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF TEXAS

Tyler White
TYLER S. WHITE
ASSISTANT UNITED STATES ATTORNEY